

REMARKS/ARGUMENT

The Office Action rejects Claims 1-14 under 35 U.S.C. §112, first paragraph. It asserts that there is no support in the specification for the retention structure forming a closed loop defining a plane that is generally lateral to the longitudinal axis of the flexible shaft and that the structural limitation, i.e., the closed loop defining a plane that is generally lateral to the longitudinal axis of the flexible shaft, therefore, constitutes new matter. This rejection is strongly traversed. Applicant would respectfully direct the attention of the Examiner to column 3, line 66 through column 4, line 7 where it is stated:

"The tension structure 14 comprises a **closed loop** at the distal end of the shaft non-concentrically disposed about shaft 12. Retention structure 14 may be integral with the shaft 12 or a separate element that is secured to the shaft 12. Figure 2 shows a proximal end view of device 10 of Figure 1 illustrating an embodiment of the non-concentric relationship of shaft 12 to retention structure 14. Retention structure 14 projects **in a generally lateral direction** from the shaft and is typically non-concentrically disposed about shaft 12." (Emphasis added.)

In view of this clear teaching in the specification and in Figures 1 and 3 of the drawings, the rejection under 35 U.S.C. §112, first paragraph, must be withdrawn.

The Office Action further rejects Claims 1-2 and 4-12 under 35 U.S.C. §103(a) as being unpatentable over applicant's earlier patent 5,738,654 in view of U.S. Patent 365,969 to Collins. This rejection is also respectfully traversed. Independent claim 1 recites *inter alia* a retention structure formed on a distal end of a flexible shaft having the form of a **closed loop** defining a plane that is generally lateral to a longitudinal axis of the shaft and where the longitudinal axis is offset from the center of the closed loop so as to pass through the perimeter of the closed loop. The retention structure shown in the Tihon '654 differs substantially from the arrangement claimed in the subject application. First of all, the retention structure 22 in the Tihon '654 patent is an open loop and not a closed loop. Further, the open loop is generally concentric with the longitudinal axis of the shaft rather than being offset so as to pass through the perimeter of the closed loop as required by independent claim 1.

While the Examiner recognizes that Tihon '654 does not disclose a closed loop, he asserts that Collins '969 shows an incontinence device comprising a closed loop and that, therefore, it would be obvious to modify the Tihon '654 device to provide a closed loop. This combination does not render applicant's claim 1 obvious within the meaning of 35 U.S.C. §103(a). First of all and contrary to the assertion made in the Office Action, Collins does not disclose a incontinence prevention device. Instead, it depicts a vaginal expanding and cleansing instrument. The arms J do not form a retention device for holding the shaft E in place in a patient's urethra. The arms J in the Collins reference do not form loops but, instead, are six separate strips each having first and second ends where the first ends are captured and affixed to the distal end of the shaft E while the second ends fit into a ring L that may slide longitudinally along the shaft to effect bowing of the arms J. Even if it is assumed, *arguendo*, that Collins relates to analogous art, which is questionable, persons skilled in the art would not be motivated to modify the Tihon '654 patent in the manner suggested in the Office Action.

The motivation for the modification suggested in the Official Action is very tenuous. There is no reason why a urinary incontinence device of the type described and claimed in the Tihon '654 patent should be made to "press against the vagina". The retention device in applicant's invention is designed to reside in the urinary bladder, not in the vagina.

For the reasons advanced, then, it is submitted that independent claim 1 is patentable over the cited prior art and should be allowed. With the allowance of independent claim 1, dependent claims 2-11 also become allowable.

For much the same reason that claim 1 is neither anticipated nor rendered obvious by the combination of Tihon '654 in view of Collins '969, independent claim 12 should also be deemed patentable. Neither of the cited references describes an apparatus that includes a shaft and a retention structure where the retention structure forms a perimeter of a **closed loop** defining a plane that is **generally lateral** to a longitudinal axis of the shaft and where the longitudinal axis of the shaft is **offset from** a center of the closed loop and **passes through the perimeter of the closed loop**. Applicant's claimed arrangement offers a technical advance over his earlier design described in the '654

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patent. The retention device, when offset in the manner claimed, better accommodates the shape configuration of the urinary bladder proximate the bladder neck, all as explained in the subject application.

In that it has been shown that independent claims 1 and 12 are fully supported by applicant's specification and drawings as filed and that no "new matter" has been introduced and because persuasive reasons have been advanced pointing out the differences between the claims at issue and the cited prior art, it is submitted that all of the claims are now in condition for allowance and a Notice to that effect is respectfully solicited.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that the foregoing Request for Reconsideration filed in response to the Official Action of August 8, 2005, in application Serial No. 10/621,243, filed on July 15, 2003, of Claude Tihon entitled "Female Incontinence Prevention Device" is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to: Mail Stop Non-Fee Amendments, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, postage prepaid, on October 27, 2005.

Date of Signature: October 27, 2005.



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